

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA  
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;  
MONTANA ENVIRONMENTAL  
INFORMATION CENTER; and CITIZENS  
FOR CLEAN ENERGY,

*Plaintiffs,*

v.

U.S. ENVIRONMENTAL PROTECTION  
AGENCY; and ANDREW R. WHEELER, in  
his official capacity as Administrator of  
the U.S. Environmental Protection  
Agency,

*Defendants.*

Case No.: 4:21-cv-00003-BMM-JTJ

The Honorable Brian Morris,  
Chief Judge

**DECLARATION OF JOHNNYE LEWIS, PH.D.**

I, Johnnye Lewis, declare as follows:

1. My name is Johnnye Lewis. I am a Research Professor at the University of New Mexico in the College of Pharmacy, Department of Pharmaceutical Sciences. I am the Director and Founder of the Community Environmental Health Program (CEHP) in the College of Pharmacy. I am also a Director of the Center for Indigenous American Environmental Health Equity Research (Indigenous EH Equity), a partnership including Crow, Sioux, and Navajo communities and agencies; and of the Navajo Birth Cohort Study/Environmental influences on Child

Health Outcomes (NBCS/ECHO), a community-driven study begun to examine how environmental exposures affect birth outcomes and child development on the Navajo Nation, and now also part of the national NIH ECHO multisite initiative; and Director of the UNM METALS Superfund Center—the first Superfund Research Center focused entirely on Indigenous communities.

2. The focus of my research over my more than 30 years as a toxicologist has been on understanding the environmental causes of chronic disease in communities, and to partner with communities, governments, and clinical care providers to develop evidence-based strategies and take actions to mitigate exposures and lower the prevalence of related disease. I have focused in particular on environmental exposures in Indigenous communities. More than 100 peer-reviewed papers on these issues have resulted from these community-partnered initiatives over the course of my career.

3. For more than 30 years, I have worked on Navajo uranium exposure and health issues, initially as a consultant to the U.S. Department of Energy developing Indigenous American risk scenarios and baseline risk assessments for Uranium Mill Tailings Remedial Action sites on tribal lands; then, through one of the first NIEHS Environmental Justice grants, collaboratively developing the Diné College Uranium Education Center; and, more recently, as Principal Investigator for the community-based DiNEH Project examining, for the first time, community

uranium exposures and health outcomes in older generations with chronic exposures. I have facilitated and developed tribal risk assessment scenarios in USEPA Regions 6, 8, and 9 working with state, tribal, and federal agencies, as well as communities.

4. The research centers that I currently direct—Indigenous EH Equity, NBCS/ECHO, and UNM METALS—all have a specific emphasis on uranium- and mine-waste exposures on tribal lands. I have led a cooperative team that includes health scientists, toxicologists, geochemists, geographers, engineers, statisticians, NGOs, community researchers, Navajo Area IHS, and Navajo Division of Health to design and obtain approval for research protocols, and implement and analyze results from three generations of Indigenous cohorts. Through my decades of work with tribal populations, I have come to have an understanding of the complexity of cultural and environmental contributors to health in tribal populations; an appreciation of jurisdictional complexities; and an ability to facilitate working relationships respectful of those boundaries which rely heavily on establishing mutual trust relationships.

5. My work conducting public-health-focused toxicology research in partnership with communities has been recognized locally and nationally by environmental and public health agencies, including appointment to the regional Air Quality Control Board; co-leadership of a Kellogg Foundation-funded

Environmental Health Task Force reporting to the New Mexico Secretaries of Health and Environment; and invited testimony to Tribal Councils, state legislative committees, and Congressional committees. I have held an elected office in the Society of Toxicology, and served on a Blue-Ribbon Panel to the NIH director and on the team selected to review and make future programmatic recommendations on the NIEHS Superfund Basic Science Research and Training Program. I was awarded the Griff Salisbury Award by NM Environmental Law Center for developing and defending a community-based recommendation reducing the uranium groundwater standard by orders of magnitude, and have just been awarded the 2021 Public Communication Award by the national professional association for toxicologists, the Society of Toxicology.

6. My spouse and I are members of the Environmental Defense Fund and have long supported its mission through donations and otherwise. As a scientist, and a toxicologist in particular, I share EDF's mission of using science to inform action to address environmental issues and to protect the health of affected populations. An important aspect of my work is collecting scientifically sound data and translating results effectively to government agencies, including the EPA, to inform evidence-based environmental and public health decisions. I make this Declaration as an EDF member and in my individual capacity and do not intend to represent the views of my funders, employers, or others.

7. I am familiar with the new EPA rule “Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information” published in the Federal Register on January 6, 2021, which addresses how EPA may consider or rely upon studies which assess “the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect” on human health in setting standards or developing “influential scientific information.” *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the “Rule”).

8. I am deeply concerned that the Rule misrepresents the concept of transparency in science. Transparency in reference to science does not rely on access to individual pieces of data, many of which are protected by a body of laws that has developed to ensure populations that their privacy will be protected if they participate in research. Instead, the validity and transparency of science relies on the transparency of methods, compliance with federal laws on conducting research in human populations, and the transparency of analytical methods used. That occurs through review by other scientists (peer-review), review by Institutional Review Boards (IRBs) charged with protecting individual rights to privacy, and the clear description of the data used in the analyses so other investigators can replicate the work. Replication is done through evaluation of appropriateness of the methodology, not simply taking the raw data and showing it can be run through the same code to

get the same results. The Rule’s misguided understanding of transparency will have real adverse consequences, impairing our recruitment of research subjects and communities and reducing the representation of Indigenous and other marginalized communities in research.

9. To begin with, ensuring confidentiality—and trust that researchers will respect it—is key to obtaining community and participant consent for involvement in population research. In my experience, study participants—particularly members of historically oppressed or disenfranchised communities, such as Indigenous communities—have learned to become wary about how information about them is used, particularly by government agencies who have not always acted in their best interests. In the cases of Indigenous sovereign nations, protections on how information on tribal members is gathered and used have been codified into policies and laws to protect individual and tribal rights.

10. In some communities this is based on fear of individual abuse, such as the cases that led to federal research policies requiring training on human research ethics for all investigators supported by federal funding. A key example is the Tuskegee Syphilis Study which hid the fact that Black participants were studied for the “natural course of syphilis,” and denied treatment they were led to believe they were receiving. In other communities, distrust of research stems from violation of the scope of specific research consents. For instance, in one case, study participants who

were members of the Havasupai Tribe consented for researchers from Arizona State University to use their biological samples to study diabetes—but the researchers ultimately conducted secondary genetic analyses of those samples, and used those analyses to publish on tribal migration, inbreeding, and schizophrenia without permission from the tribe or individual participants. Although the tribe won the resulting court settlement, damage to its members' privacy rights couldn't be undone—and continuing concerns among Indigenous populations about the use of data beyond their consent have made it more difficult to recruit Indigenous people in future research, leading to bias on the applicability of research-based decisions to Indigenous or other vulnerable populations.

11. As I have discovered over decades of research, because of these concerns, members of Indigenous communities are often very reluctant to participate in any study or provide any information about themselves out of fear of how that information may be used, or misused, against them. It is critical, especially when working with these communities, that population researchers be able to assure study participants that their participation and associated data will remain confidential to be able to conduct the scientific work often necessary to help solve the very problems that contribute to disparities in health.

12. But over time, we have come up with an approach to navigate these challenges. Population studies are always designed and carried out to prevent the

disclosure of confidential and personal information about individual study participants. The specific measures to protect the privacy of study participants in population health studies are reviewed, modified, and approved by review boards generally called Institutional Review Boards, or IRBs. These boards are certified federally, and increasingly Indigenous nations have established their own federally recognized review boards, or other processes to ensure tribal privacy laws are respected by proposed research. A given study, therefore, may be subject to more than one IRB. For example, a researcher may need IRB approval from her own university, from an additional IRB providing review for large multi-institutional studies, as well as from a tribal IRB (or tribal equivalent) to assure compliance with tribal laws to protect both the privacy of tribal members and the treaty rights granted by the US government to these sovereign nations. In these cases, the sovereignty of the tribal nation also mandates that the data remain the property of the tribe, and that all data are used by the researcher under the strict protocol approved, and returned to the tribe once the study is complete, with tribal review before final publication in peer-reviewed scientific journals as well.

13. The measures tribes implement (whether through IRBs or otherwise) to protect against the misuse and disclosure of confidential information about the tribe and its members are often referred to as “data sovereignty.” These measures are notably strict. By way of illustration, in a recent study involving the Navajo Nation,

nearly 2.5 years of negotiation were required to establish adequate data protection by the joint data analysis center for a multisite federal study to ensure the terms of the tribal research policy, the privacy of tribal members, and the other terms of approval of the research would be protected while allowing for data to be compared in analyses to other sites in the study to better inform the understanding of needs in the population.

14. In addition to IRB conditions, the need to protect research participants' privacy has been recognized and supported by state and federal laws, such as HIPAA, as well as by agreements with study participants acknowledged in the study consent forms approved by federally certified IRBs.

15. Trust is a key factor in all of this; we cannot do our work without it. It is essential to obtaining approval from tribal IRBs, obtaining agreements with tribes to perform research studies, and obtaining consent from individuals to participate in studies. Building that trust takes years of work and a proven history of honesty and meeting commitments. I have worked with the Navajo Nation and several other Indigenous communities for over 25 years on health-related issues and have built their trust that I will keep their personal information confidential and honor the letter and the spirit of the agreements we enter into. Without that trust, I would not be able to obtain the approvals necessary to collect and use the data. And even with that

trust, obtaining approvals requires thoughtful design of protocols, is sensitive, and takes time and care.

16. Over the past 20+ years, the scientific research community has developed a substantial awareness of these trust issues. As environmental justice has developed as an area of interest for research and as Indigenous nations have established the need for tribal consultation by federal agencies for decisions impacting their health and culture, both peer reviewers of grants and decision-makers in funding agencies have an expectation that proposals will demonstrate the investigative team's ability to conduct the research—and especially the team's sensitivity to community trust. Proposals require letters of support for the relevance of the research to the community and a plan to ensure the privacy and protection of culturally sensitive information while conducting valid scientific protocols. In my experience, none of this would be possible without a community's underlying trust that I can and will protect the confidentiality of the data I collect. Nor would I be able to get the support and consent of the tribes or individuals to participate in the study or collect the data without these guarantees.

17. But while the hard-won trust of tribal communities must be built up over decades, it can be easily lost in a moment. If I can no longer demonstrate that individual-level data will not be disclosed or will not be provided to EPA or other entities, I and my teams will lose the mutual trust we have developed with community

partners, and lose the willingness of both the tribal government and the individual community members themselves to participate in research. By its nature, trust once lost can be virtually impossible to regain.

18. But this is precisely the problem the EPA's Rule introduces. Indigenous communities participate in research because they want results to inform policies that protect their health and environment. But if according the results full weight in decisions also requires loss of privacy and confidentiality protection, or loss of ownership of data, that loss of sovereign protection will jeopardize participation.

19. And the Rule, and the loss of trust it occasions, will have even more far-reaching consequences. There is currently a strong need to achieve greater diversity in research populations to better expand the generalizability of the toxicologic research that informs our understanding of risk across populations. But losing the trust of these communities will make it very difficult to plug this gap, discouraging communities—including those targeted by active programs currently in development—from working with researchers to meet this need. And the problem is likely to persist. If trust between researchers and communities is damaged, these relationships are not quickly rebuilt, and we are likely to continue facing difficulties ensuring that research in under-studied communities goes forward. Accordingly, by reducing the willingness of vulnerable populations to participate in scientific research and blocking opportunities to understand unique responses to toxicants within these

populations, the Rule will impair our ability to develop evidence-based policies protective of these and other vulnerable populations. As a result, the research used to inform decisions will continue to fail to include the full range of populations and communities affected by those decisions. Exclusion of specific sectors of the population from the general body of science informing decisions and policy produces a strong chance of bias in the data and resulting policy, and a high risk of policies that fail to protect specific populations with unique practices or sensitivities that would produce alternate results if included.

20. These problems will immediately affect my own work. Our research centers employ approximately one hundred people, many of them members of Indigenous communities. The funding used to employ these people comes primarily from grants from several institutes at the National Institutes of Health, with a significant portion of funding tied to our UNM METALS Center.

21. Currently, UNM METALS is working with communities on Laguna Pueblo near the abandoned Jackpile uranium mine on the Superfund National Priorities list, as well as several communities on Navajo Nation where abandoned uranium mine waste from more than 520 mines active during the Cold War is being addressed under CERCLA emergency response authority through the USEPA Five (and now Ten) Year Plans to Address Uranium Contamination on the Navajo Nation. By understanding the detailed environmental conditions at these sites, as

well as the relationships between exposures and health effects, the METALS research is focused on developing novel remediation approaches and clinical interventions that reduce toxicity, provide cost-effective and sustainable solutions for remediation, and improve health. An initial clinical trial to reverse DNA damage has already begun. UNM METALS's work is being funded in part by a multi-year grant from the National Institute of Environmental Health Sciences. My team and I are preparing a proposal to continue that funding, which provides significant support for the UNM METALS team, for submission in February 2021 as part of a call for proposals that occurs every two years. As many as 40 research teams working on questions affecting Superfund sites and vulnerable exposed populations across the country are expected to respond.

22. In UNM METALS's research, individual-level data are collected while monitoring health and exposures in communities. Analyses to develop conclusions require large numbers of individuals in the population for validity of the science. Studies reporting only "case studies," or work based on a single individual, would not be considered representative of the population and sufficient to inform decisions. For the peer review conducted for publication in scientific journals, the summary-level analyses that form the basis for our understanding of the relationships between exposures to contaminants and toxicity need to be representative of the affected populations. That peer review and determination of validity will be based on the

details of the methods used to collect the data and the analyses performed. Considerations include study details like how participants in the study were identified, whether as a whole they represent the population or are biased in some way, whether they understood the research that was being conducted, and whether valid methods were used to analyze the data. To pass muster, the data need to include a range of ages, men and women, rich and poor, and the racial and ethnic make-up of those who will be influenced by the results to be generalizable to that population. By contrast, the data related to a given individual in that group will not be the basis for drawing any valid conclusions.

23. Much information that is collected in clinical trials, or from medical record review, is clearly very personal and sensitive. In my experience, that is the kind of personal information that Indigenous, and most other, communities and individuals view as particularly private and sensitive and that Indigenous communities by right of sovereignty protect through IRB conditions and other agreements. If we cannot commit to keep the underlying data confidential, the tribes are not likely to continue to provide access to the data and their members will be unlikely to consent to participate, placing the entire study, and grant, in jeopardy, and also resulting in tribal-specific data being unavailable to inform decisions on tribal land. It is unlikely that we could obtain IRB or tribal approval to disclose that confidential data to EPA. Conversely, however, if we cannot explain that EPA will

be able to place due weight on the results of the study to inform its policy and decision-making, it is unlikely that my team's proposal will meet the expectations of the funding agency, or the partnering tribes and communities. These competing demands—between the confidentiality necessary to perform the work and the disclosure that would be necessary for results to be used to inform EPA decisions, and therefore to receive funding for the work—are untenable.

24. Proposals for large centers such as UNM METALS that are meant to address complex issues through multidisciplinary team science require many months of preparation. The work proposed is developed in consultation with the communities and tribes involved to identify gaps in knowledge, requires access agreements and support from the tribes and communities, and requires integration across 9 individual projects that learn from each other and ultimately develop perspectives not possible within individual research projects.

25. Currently, UNM METALS is preparing a proposal seeking a >\$10 million 5-year grant to the National Institute of Environmental Health Sciences in response to their CERCLA mandate to develop science that informs USEPA's CERCLA responses. That proposal is due on February 15, 2021, and the components are in close-to-final draft form and out for review by external advisors to inform final edits. Budgets for research components and subawards to collaborating institutions and NGOs are being finalized. The proposal is dependent on continued access to

data and participation from the Navajo Nation and Laguna Pueblo. But because of the Rule, it will now be much more difficult to obtain that access. I now must explain to the tribes and their members that I would be required to provide underlying individual data from the research studies to EPA in order for the data to receive full weight in EPA decision-making. And not only are they unlikely to consent to that arrangement, but posing the choice risks destroying the trust I have built up over many years and thereby losing the trust of the tribe and individuals permanently. All this—plus the EPA Rule’s sudden effectiveness— means we face the immediate challenge of scrambling to figure out how to rebuild the study (well over 1000 pp) to somehow be able to answer the questions on toxicity resulting from exposures while accommodating both EPA requirements and tribal concerns. This will take enormous time and effort. And it is extremely unlikely that such changes could be made in time to meet the February 15 deadline, jeopardizing the funding of the more than 65 people funded by this center alone, and the expectation of partner communities to improve the understanding of these situations and possible options to reduce hazards and improve health.

26. If UNM METALS were to lose the existing NIEHS grant, or not obtain the additional grant, UNM METALS would face an immediate financial crisis and be forced to lay off much, if not all, of its work force.

27. And science itself will suffer. If these tribal-specific and site-specific data are NOT included in decisions, the decisions will not be based on the best and most relevant data to protect the populations.

28. This goes beyond just my work and the specific grants discussed above. Once tribes and other communities learn that researchers in general cannot promise to both keep the individual data confidential and still provide actionable data to EPA, researchers lose not only their funding and the opportunity to apply their research expertise to help solve these complex problems, but also lose the trust they have built up over the years and access to those communities and individuals needed for science to be truly representative of the populations affected by research results—a goal we must achieve to ensure the validity of research and the ability to generalize results to specific populations. Further, researchers will face additional challenges gaining the trust of new communities to conduct new research if protection of individual and tribal privacy policies cannot be guaranteed. In either case, without the ability to protect confidential data, population researchers will not be able to perform the kind of work necessary to document the health impacts of pollution and inform decisions by EPA to address those critical environmental health issues and protect the health of communities.

29. The Rule also jeopardizes my ability carry out the work that is so important to me personally and professionally. In my decades of working with

communities and with agencies involved in decision-making that affects environmental quality and population health, I have learned how important it is to maintain communication and partnership with all parties involved to ensure that communication is effective. In doing these large multi-disciplinary, multicultural projects, one role I have always played is to bridge disciplines and cultures, keep people at the table and discussing concerns, translating to make sure that intentions are accurately heard by audiences, and that effective communication continues across involved parties. The situations I work in are often emotionally charged, and frustrations resulting from decades of inaction on one side, and constraints on what is possible to accomplish on another, further increase tensions. As someone who has had a very diverse history in working with diverse communities, academic research, and regulatory agencies, and tried hard to build strong and trusted partnerships, it is important to me to be able to continue the work we have started to contribute to resolving these complex situations. My professional career, and a large part of my personal life, have been committed to these goals, and I feel very responsible for those who work as part of my research teams, and to those in communities who have trusted our ability to find answers to these challenging questions. Losing that base that has taken decades to build would create enormous personal and professional loss.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

A handwritten signature in black ink, appearing to read "J. Lewis", enclosed within a thin black rectangular border.

Dated: January 8, 2021

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Johnnie Lewis